

REMARKS

After entry of this amendment, claims 1–40 will be pending; claims 8–21, 23–29, and 31–36 are withdrawn in response to a restriction requirement, claims 22, 30, and 37 are canceled, and claims 38–40 are new. Claim 1 has been amended for clarification of the scope of the claim. No new matter has been added; support for the amendments and new claims may be found, for example, on page 37, lines 5–10 and lines 15–17, page 37, lines 4–6, page 38, line 15 – page 39, line 1, page 41, lines 19–22, and page 42, lines 9–13 of the specification.

Rejection of Claims Under 35 U.S.C. § 112

Claims 1–7 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly the specification is not enabling for the invention commensurate in scope with these claims.

Without acquiescing to the rejection and to expedite prosecution, claim 1 is amended to clarify the relationship of the membrane layers to each other, as well as the features distinguishing the inner layer from the outer layer. Accordingly, Applicants submit that claim 1, as amended, provides structural relationships between and structural features of the layers of the claimed composite membrane that are sufficient for a skilled artisan to make and use the claimed invention, which is commensurate in scope with the specification. Dependent claims 38–40 have been added to further define features of the claimed invention.

Applicants further submit that claim 1, as amended, is enabled by the specification, at least because

[a] single embodiment may provide broad enablement in cases involving predictable factors, such as mechanical or electrical elements.

MPEP, Eight Edition, Revised May 2004, § 2164.03, citing *In re Vickers*, 141 F.2d 522, 236-27 (CCPA 1944); *In re Cook*, 439 F.2d 730, 732 (CCPA 1971).

The claimed structure is a mechanical device that includes predictable elements, rather than unpredictable elements such as those that occur in the chemical arts. More specifically, the claimed subject matter is a mechanical apparatus, i.e., a composite membrane for a biosensor that includes predictable elements such as membrane layers spatially arranged in a particular manner, as recited in amended claim 1. Although each of the layers comprises a chemical entity, this fact

does not place the claimed subject matter in the chemical arts. After all, all mechanical devices comprise components that are made from one or more chemical substances.

Moreover, the specification describes a number of possible embodiments of the claimed structure. For example, the outer membrane layer may include one or more polyurethane-based compounds. See page 37, lines 16–17. The inner membrane layer may include various monomers, such as benzothioiophene, phenylenediamines, and/or phenols. See page 41, lines 18–19. The enzyme layer may include various types and combinations of enzymes, cross-linking agents, and enzyme stabilizers. See page 39, line 3 – page 41, line 14. The claimed structure, therefore, is fully enabled by the specification such that one of skill in the art can make and use the entire scope of the claimed invention without undue experimentation.

Accordingly, for the above reasons, Applicants respectfully request that the rejection of claim 1, and claims 2–6 which depend therefrom, be reconsidered and withdrawn.

Claims 1–7 stand rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite. Independent claim 1 has been amended to recite the relationship of the inner, outer, and enzyme layers to each other. Accordingly, Applicants respectfully request that this rejection of claims 1–7 be reconsidered and withdrawn.

Rejection of Claims Under 35 U.S.C. § 103(a)

Claims 1–7 stand rejected under 35 U.S.C. § 103(a) as being allegedly unpatentable over Mansouri et al. in view of U.S. Patent No. 5,262,305 to Heller (“Heller”) and Madaras et al, “Miniaturized Biosensors Employing Electropolymerized Permselective Films and Their Use for Creatinine Assays in Human Serum,” *Anal. Chem.* 1996, 68, 3832-3839 (“Madaras”), and Chen et al., “Stability of Oxidases Immobilized in Silica Gels,” *J. Am. Chem. Soc.* 1998, 120, 4582-4585 (“Chen”). In particular, the Examiner recognizes Mansouri does not disclose an enzyme layer including a matrix comprising an enzyme, a cross-linking agent, and an enzyme stabilizer, and relies on Heller and Madaras to provide these features. The Examiner also recognizes that Mansouri does not teach enzyme layers containing lactate oxidase, creatinase, sarcosine oxidase, and creatininase, and relies on Heller, Madaras, and Chen to teach biosensors including these enzymes.

Applicants respectfully submit that neither Mansouri nor any of the other cited art, neither alone nor in combination, teach or suggest a composite membrane having the composition recited in amended claim 1. Namely, these references do not teach or suggest a composite

membrane including an outer layer comprising polyurethane and an inner membrane layer comprising a restorable polymerizable membrane. For example, Mansouri is silent regarding the composition of a three-layer composite membrane. Furthermore, Madaras discloses an outer layer formed by using mixtures of p-HEMA, Nafion, and methanol. See Madaras, page 3834, section "Outer Membrane."

In view of the remarks set forth above, Applicants submit that the rejection under 35 U.S.C. § 103(a) of claim 1, as amended, should not be maintained. Accordingly, reconsideration and withdrawal of the rejection of this claim and claims dependent therefrom under U.S.C. § 103(a) a unpatentable over Mansouri in view of Heller, Madaras, and Chen is respectfully requested.

Information Disclosure Statement

Enclosed is a Supplemental Information Disclosure Statement, a PTO-1449 form, and copies of cited references. The PTO-1449 form lists two references previously cited to the Patent Office, copies of which were not received by the Examiner. The Examiner is requested to consider the references and to return the initialed PTO-1449 form to the undersigned attorney.

CONCLUSION

In light of the foregoing, Applicants respectfully submit that all claims are now in condition for allowance.

Applicants believe that all required fees have been paid. However, if any fee is necessitated by this paper, please charge the fee to our Deposit Account No. 20-0531.

If the Examiner believes that a telephone conversation with Applicants' attorney would expedite allowance of this application, the Examiner is cordially invited to call the undersigned attorney at (617) 310-8327.

Respectfully submitted,

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